

43. (new) The method according to claim 36, wherein said biocompatible biomaterial further comprises at least another biocompatible natural, semisynthetic and/or synthetic polymer.

44. (new) The method according to claim 36, wherein said biocompatible biomaterial further contains pharmaceutically or biologically active substances.

45. (new) The method according to claim 36, wherein said biocompatible biomaterial further contains inside the non-woven fabrics, cords and liophylic compositions.

REMARKS

The finality of the Restriction Requirement has been noted.

Formal drawings will be provided when the application is allowed.

Claims 1 and 26-35 have been canceled and new claims 36-45 have been added to point out the invention. The new claims have been drafted to avoid the rejections that were entered with regard to the canceled claims.

Claims 1 and 24 were rejected under 35 U.S.C. §102(b) as being anticipated by Dorigatti et al.

Reconsideration is requested.

Dorigatti et al. teach non woven fabric biomaterials that comprise esters of hyaluronic acid (hereinafter referred to as HA) for use in surgery to aid in the regeneration of tissues.

The Examiner has urged that Dorigatti et al. teach biomaterials which comprise HA esters having less than 85% of the groups esterified. The Examiner has based this assertion in particular on Example 1 (50% of the carboxylic acid groups esterified), Example 7 (75% of the carboxylic groups esterified) and Example 15 (85% of the carboxylic acid groups esterified).

Contrary to the Examiner's contentions, the biomaterials disclosed by Dorigatti et al. are comprised of total esters or partial esters of HA, having a degree of esterification that is higher than 85%.

The Examples of Dorigatti et al. that have been cited by the Examiner are titled as: "Preparation Examples", which "exemplify the preparation of hyaluronic acid esters useful in the composite membranes of the invention" (see Dorigatti et al., page 18, lines 14-17), whereas the non woven biomaterials of the invention according to Dorigatti et al. are described in Examples 27-31 at pages 36-39.

Examples 27-31 of Dorigatti et al. constitute the proper basis for comparing the claimed non woven biomaterials of the present invention with the prior art. Examples 1-26 do not represent the closest prior art to the claim non woven biomaterials.

The following Table shows that Examples 27-31 of Dorigatti et al. describe materials based on HA esters, which are total esters or partial esters having an esterification degree higher than 85%:

TABLE

	HA derivative contained in the biomaterial	(amount %)	esterification degree(%)
EXAMPLE 27	HA benzyl ester HYAFF® 11	(100%)	100%
EXAMPLE 28	HA ethyl ester HYAFF® 7	(100%)	100%
EXAMPLE 29	HA ethyl ester HYAFF® 7	(50%)	100%
	HA benzyl ester HYAFF® 11	(50%)	
EXAMPLE 30	HA benzyl ester HYAFF® 11	(50%)	
	HA part.benz.ester HYAFF® 11p75	(50%)	87.5%
EXAMPLE 31	HA benzyl ester HYAFF® 11	(100%)	100%

The Examiner is requested to note that Example 30 describes the preparation of a non woven fabric material containing a mixture of HA totally esterified with benzyl alcohol and of HA partially esterified (75%) in equal percentages. The resulting degree of esterification of the biomaterial may be calculated as follows: $(100+75)/2 = 87.5\%$, i.e. higher than 85%. All other Examples refer to the preparation of biomaterials based on totally esterified HA.

Nothing in Dorigatti et al. makes obvious the making of non woven biomaterial of esterified HA having a degree of esterification of less than 85%. There is no direct or implied teaching to make a non woven biomaterial having a degree of esterification of less than 85% (claim 36). Therefore, Dorigatti et al. cannot anticipate the method of using hyaluronic acid esters processed in the form of non woven tissue and having an esterification degree lower than 85% as claimed in claim 36. For these reasons, it is requested that the rejection for anticipation not be applied to reject the newly presented claims.

Claims 1 and 24-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dorigatti et al.

Reconsideration is requested.

As stated supra, the non woven material of method claim 36 has an esterification degree lower than 85%. In Examples 1, 2 and 4 of the present application, as originally filed, comparative experiments are disclosed which compare non woven tissues based on totally esterified HA and non woven tissues comprising HA esters having a degree of esterification lower than 85%.

These experiments prove that HA esters processed in the form of non woven tissue that have an esterification degree lower than 85%, induce a higher re-epithelialization and a greater degree of bone regeneration than the total esters of HA having the same structure.

The results of these experiments are illustrated in the Figs. 1-3 of the drawings as originally filed, wherein the degree of esterification of the partial esters is indicated as "px" after the commercial name of the product (for example, HYAFF 11p65 has an esterification degree of 65%).

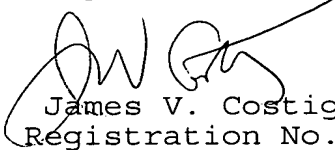
In particular, from Fig. 1 it is evident that the percentage of newly formed bone is substantially higher when the partial esters HYAFF 11p80 or HYAFF 11p65 are used than in the case the material is made of the corresponding total ester HYAFF 11. Analogous results are reported in Fig. 3, wherein the total ester HYAFF 11 and the partial ester HYAFF 11p75 are compared for non woven materials at three different times after surgery.

In Fig. 2, the percentage of re-epithelialization is illustrated for non woven tissue made of HYAFF 11p65 in comparison with the corresponding HA totally esterified derivative HYAFF 11, and the superiority of the former non woven tissue is evident.

The experimental results reported in the present application demonstrate that the claimed value of the esterification degree of the biomaterial provides improved bone regeneration and re-epithelialization. Therefore, these results rebut any inference of obviousness that could be inferred from the prior art. For these reasons, it is requested that this ground of rejection not be applied against the newly presented claims.

An early and favorable action is earnestly solicited.

Respectfully submitted,


James V. Costigan
Registration No. 25,669

HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036-2646
(212) 302-8989

I hereby certify that this
correspondence is being
deposited with the United States Postal Service as
first class mail in an envelope addressed to:
Commissioner for Patents,
Washington, D.C. 20231, on 2/6/03

